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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,425	01/26/2001	Xaveer Van Ostade	4644US	8053

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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/771,425	OSTADE ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11,14,15,18,21-24,26 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-11, 14, 15, 18, 21-24, 26, and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicants' amendment filed on September 27, 2004 has been entered in full. Claims 1, 5, 7-8, 10, 11, 15, 18, and 21-24 have been amended. Claims 16 and 25 have been canceled. Claims 26 and 27 have been added. Claims 1, 3-11, 14, 15, 18, 21-24, 26, and 27 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

The objection to abstract of the disclosure due to the presence of typed materials, which are not related to the disclosure has been withdrawn in view of the amendment to the abstract.

The rejection of claims 11, 16, 24, and 25 under 35 U.S.C. 112, 2nd paragraph set forth in the record (Paper No. 20) has been withdrawn in view of the amended and canceled claims.

Claim Rejections Under 35 U. S. C. § 112, 2nd paragraph

Claim 22 is rejected under 35 U.S.C. 112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites the limitation "said second recombinant gene" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections Under 35 U. S. C. § 103 (a)

(i) The rejection of claims 1, 3-6, 10, 11, 14, 15, 18, and 21-24 under 35 U.S.C. 103(a) as being unpatentable over Pestka et al. (WO 98/02558, January 22, 1998) in view of Trueheart et al. (*IDS*, WO 98/13513, April 2, 1998), set forth in Paper No. 20, is maintained. New claim 26 is also rejected on the same basis. It is noted that Pestka et al. teach a chimeric receptor comprising the intracellular domain of IFNα receptor (see e.g., Abstract, Figures 2-3).

Beginning at page 9 of the response, Applicants argue that a *prima facie* case of obviousness cannot be established with regard to any of independent claims 1, 15, and 24, as amended, since the cited references do not, alone or in combination, teach or suggest the limitation "a recombinant reporter system".

This has been fully considered but is not deemed to be persuasive because while the Examiner agrees with Applicants that Pestka et al. does not teach a recombinant reporter system, Trueheart et al. do teach that the use of a reporter or indicator gene can provide a convenient readout (page 3, the second paragraph). Trueheart et al. teach constructing recombinant reporter genes (beginning at page 67). Trueheart et al. clearly states "signal transduction can be measured in a variety of ways" and "by whatever means measured, a change (e.g., a statistically significant change) in the detection signal can be used to identify novel compounds which function as receptor agonists or antagonists" (page 3, the second paragraph). Thus, the cited references in combination teach or suggest each and every element of the amended claims.

At the bottom of page 10 of the response, Applicants argue that no suggestion or motivation exists to combine the disclosure of Pestka et al. with Trueheart et al. Applicants submit that Pestka et al. do not describe any screening system and thus, one of ordinary skill in the art would not be motivated to modify Petka et al. or combine Pestka et al. with Trueheart et al. in order to arrive at the mammalian cell of claim 1, the method for identifying an agonist as recited in amended claim 15 or the method for identifying an antagonist as recited in amended claim 24. Rather, Pestka et al. intended to develop an assay system for a given cytokine or to reconstitute responsiveness to a soluble factor. In either instance, Pestka et al. starts with a well kown ligand, not a complex mixture of unknown compounds.

This has been fully considered but is not deemed to be persuasive because Applicants' argument that Pestka et al. do not describe any screening system is incorrect. As noted at page 5 of Paper No. 20 (mailed on 06/11/2003), Pestka et al. teach a method for identifying a specific ligand, an agonist, or an antagonist using routine screening techniques and a highly sensitive assay cell line that express a chimeric receptor (bottom of page 44 to page 47). Pestka et al. also teach various screening techniques, such as natural product libraries, combinatorial libraries using recombinant bacteriophage, and synthetic libraries. Moreover, as noted at page 6 of Paper No. 20 (mailed on 06/11/2003), Trueheart et al. also teach a method for screening and identifying pharmaceutically effective compounds that specifically interact with and modulate the activity of a receptor. The method enables rapid screening of large numbers of compounds to identify those that act as an agonist or antagonist to the bioactivity of the receptor (see abstract). The method enables rapid screening of large numbers of polypeptides in a library expressed in the cell in order to identify those polypeptides which create an autocrine system (page 3, last paragraph). Therefore, one of skill in the art would be motivated to combine the teachings of Pestka et al. with the teachings of Trueheart et al. to arrive at the mammalian cell of claim 1, the method for identifying an agonist as recited in amended claim 15 or the method for identifying an antagonist as recited in amended claim 24

At the first paragraph of page 11 of applicants' response, Applicants submit that the statement from first paragraph of page 8 (Paper No. 06202004, mailed on 06/24/2004)

appears to be an impermissible hindsight. The Examiner notes that this statement is response to Applicants' argument that it would take undue experimentation to combine the teachings of Pestka et al. with the teachings of Trueheart et al. to arrive at the claimed invention.

(ii) The rejection of claims 7 and 8 under 35 U.S.C. 103(a) as being unpatentable over Pestka et al. (WO 98/02558, January 22, 1998) in view of Trueheart et al. (WO 98/13513, April 2, 1998), and further in view of Pellegrini et al. (*Molecular and Cellular Biology* 9:4605-4612, 1989), as set forth in Paper No. 20, is maintained. New claim 27 is also rejected on the same basis.

Applicants argue that since dependent claims 7 and 8 include the elements of independent claim 1 and a prima facie case of obviousness cannot be established with regard to independent claim 1, a prima facie case of obviousness also cannot be established with regard to dependent claim 7 and 8. This is not found to be persuasive. As noted above, Trueheart et al. teach the use of a reporter or indicator gene and the cited references in combination teach or suggest each and every element of the amended claims. Accordingly, a prima facie case of obviousness regard to independent claim 1 and thus dependent claims 7 and 8 has been established.

At the bottom of page 11 of the response, Applicants argue that a prima facie case of obviousness cannot be established with regard to claims 7 and 8 since one of ordinary

skill in the art would not have a reasonable expectation of success in combining the cited references. Applicants further submit that one of ordinary skill in the art would not reasonably expect to be able to detect the IL-10 receptor-mediated activation of Pestka et al. with the *E. coli* xanthineguanine phosphoribosyl transferase (*gpt*) under control of a 6-16 promoter since Pestka et al. uses the natural response of the cell to detect signaling.

This has been fully considered but is not deemed to be persuasive because, as noted at page 8 of Paper No. 20 (mailed on 06/11/2003), Pellegrini et al. teach that the *gpt* reporter is under control of a 6-16 promoter in 2fTGH cells and that the 6-16 promoter is tightly regulated by α or β interferon. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the reporter system as taught by Pellegrini et al. and to express the chimeric receptors in 2fTGH cells with a reasonable expectation of success. One would have been motivated to do so because Pestka et al. teach chimeric receptors comprising an intracellular domain of an α-interfereon receptor and the *gpt* gene as a reporter under control of the 6-16 promoter is responsive to α-interfereon as taught by Pellegrini et al. It is noted that the instant claims not only encompass chimeric receptors that are responsive to IL-10 but also chimric receptors that are responsive to, for example, α-interfereon. It is further noted that while Pestka et al. do not teach a recombinant reporter system, Trueheart et al. do teach that the use of a recombinant reporter in the screening methods.

(iii) The rejection of claim 9 under 35 U.S.C. 103(a) as being unpatentable over Pestka et al. (WO 98/02558, January 22, 1998) in view of Trueheart et al. (WO 98/13513, April 2, 1998), and further in view of Mizushima et al. (Nucleic Acids Research, 18:5322, 1990), as set forth in Paper No. 20, is maintained.

Applicants argue that since dependent claim 9 includes the elements of independent claim 1 and a prima facie case of obviousness cannot be established with regard to independent claim 1, a prima facie case of obviousness also cannot be established with regard to dependent claim 9. This is not found to be persuasive. As noted above, Trueheart et al. teach the use of a reporter or indicator gene and the cited references in combination teach or suggest each and every element of the amended claims. Accordingly, a prima facie case of obviousness regard to independent claim 1 and thus dependent claim 9 has been established.

Claim Objections

The objection to claim 18 as being of improper dependent form for failing to further limit the subject matter of a previous claim is maintained. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Claim 18 recites the limitation "wherein said agonists are encoded for by the library of recombinant genes". However, such a limitation is already present in claim 15. It is also noted that there appears to be a typographic error in the limitation; "encoded for by". Correction is required.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone

number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li, Ph.D.
Examiner
November 23, 2004

JANET ANDRES
PRIMARY EXAMINER